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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

June 29, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Parklawn Drive
Rockville, Maryland 20852

E. EDWARD KAVANAUGH
P R E S I D E N T

CITIZEN PETITION

Re: FDA Publication of a Proposed Regulation to Establish
Labeling Requirements Relating to Sun Protection with Use of
Cosmetic Products Containing Alpha Hydroxy Acids

The Cosmetic, Toiletry, and Fragrance Association (CTFA) submits this petition to the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to request the Commissioner of Food and Drugs to publish in the Federal Register a proposed regulation establishing labeling requirements relating to sun protection with use of cosmetic products containing an alpha hydroxy acid ingredient that is intended to function as an exfoliant.

A. Action Requested

CTFA requests the Commissioner to publish in the Federal Register, under sections 602(a) and 701(a) of the FD&C Act, the following proposed regulation:

§ 701.40 Alpha Hydroxy Acids

The label and labeling of a cosmetic product that contains an alpha hydroxy acid ingredient that is intended to function as an exfoliant shall bear the following prominent and conspicuous statement:

"Sun Alert: Because this product may make your skin more sensitive to the sun, be certain you have adequate sunscreen protection while using this product and for a week after you discontinue use."

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CTFA requests that the proposed regulation be published as soon as possible and that any final regulation be made effective for all products introduced into interstate commerce two years following the date of promulgation of the final regulation in the Federal Register.

B. Statement of Grounds

Exfoliant ingredients have been used in consumer products for at least two thousand years. Attached as Appendix A to this petition is a memorandum, dated May 20, 1994, documenting the historical use of one category of such ingredients, alpha hydroxy acids, in cosmetic products from ancient to modern times. Data supplied to CTFA by Kline & Company, Inc. indicate that products containing alpha hydroxy acids currently represent a significant portion of the \$6 billion domestic United States skin care market. There are currently estimated to be well in excess of 1,000 – most likely 1,500 or more - stock keeping units (SKUs) of skin care products that contain alpha hydroxy acids.

Although exfoliant ingredients have been used in cosmetic products for centuries, their use increased in the early 1990s on the basis of tests demonstrating their effectiveness in cleaning dead cells from the surface of the skin and assisting moisturization. As the use of alpha hydroxy acids increased during this time, FDA personnel raised the question whether the removal of dead cells would significantly increase human skin sun sensitivity.

In response to this question, CTFA requested the Expert Panel of the Cosmetic Ingredient Review (CIR) to expedite its review and evaluation of the safety of alpha hydroxy acids. The CIR was established by the cosmetic industry in 1976 to conduct an evaluation of the safety of cosmetic ingredients, using an independent Expert Panel of highly qualified academic scientists and physicians. The curriculum vitae of the CIR Expert Panel members who reviewed and evaluated the alpha hydroxy acids data are included in Appendix B to this petition. The Director of the FDA Office of Cosmetics and Colors attends CIR Expert Panel meetings and is invited to make oral comments and submit written materials relating to any matter under discussion. The Consumer Federation of America similarly has a representative who actively participates in CIR Expert Panel deliberations.

The CIR Expert Panel reviewed the safety of the two alpha hydroxy acids for which there was documented evidence of use in cosmetics: glycolic acid and lactic acid and their salts and esters. After reviewing all published and unpublished data on these two ingredients thoroughly, including the results of testing undertaken by both FDA and CTFA, in December 1996 the CIR Expert Panel made the following safety determination

with respect to cosmetic products for personal use:

"Based on the available information included in this report, the CIR Expert Panel concludes that glycolic and lactic acids, their common salts and their simple esters, are safe for use in cosmetic products at concentrations less than or equal to 10 percent, at final formulation pH greater than or equal to 3.5, when formulated to avoid increasing the skin's sensitivity to the sun, or when directions for use include the daily use of sun protection."

The full report of the CIR Expert Panel, as subsequently published in "Final Report on the Safety Assessment of Glycolic Acid, Ammonium, Calcium, Potassium, and Sodium Glycolates, Methyl, Ethyl, Propyl, and Butyl Glycolates, and Lactic Acid, Ammonium, Calcium, Potassium, Sodium, and TEA-Lactates, Methyl, Ethyl, Isopropyl, and Butyl Lactates, and Lauryl, Myristyl, and Cetyl Lactates," *International Journal of Toxicology*, Vol. 17 (1) 1998, is attached to this petition as Appendix C.

More recently, the FDA Center for Food Safety and Applied Nutrition issued 1999 CFSAN Program Priorities (January 1999). Included in the cosmetic priorities was the following:

1. "Alpha hydroxy Acids: Complete assessment of Alpha hydroxy Acids to determine public health risk and regulatory category"

The Director of the Center for Food Safety and Applied Nutrition also wrote CTFA on March 10, 1999, stating that FDA "still sees a need for further consideration of the safety of these widely used ingredients and the need to conduct a thorough assessment of potential risks to the public health."

Again in FDA's Center for Food Safety and Applied Nutrition's CFSAN 2000 Program Priorities (February 2000), Alpha Hydroxy Acids were part of the "A List" of cosmetic priorities with an objective to "Develop proposal for labeling of AHA containing products."

CTFA is responding to the designation of alpha hydroxy acids as a program priority and to the letter from CFSAN with this petition. CTFA is responding specifically to FDA's stated desire to develop a proposal for AHA labeling. CTFA urges FDA to publish in the Federal Register a proposed regulation establishing labeling requirements relating to sun protection with use of cosmetic products containing alpha hydroxy acids.

Under the approach requested in this petition, consumers would be advised to use sun protection in accordance with the recommendation of the CIR Expert Panel, in conjunction with the use of any cosmetic product containing an alpha hydroxy acid ingredient that is intended to function as an exfoliant.

A cosmetic product meeting the definition in this regulation will contain the required labeling whether or not the alpha hydroxy acid product also contains a sunscreen. This will ensure that the consumer knows that such sun protection is important and, where an alpha hydroxy acid product containing a sunscreen is washed off, knows that sunscreen needs to be separately applied before sun exposure during the relevant period of AHA use and one week after.

C. Environmental Impact

The requested action would not significantly affect the quality of the human environment and is subject to categorical exclusions under Subpart C of 21 C.F.R. Part 25.

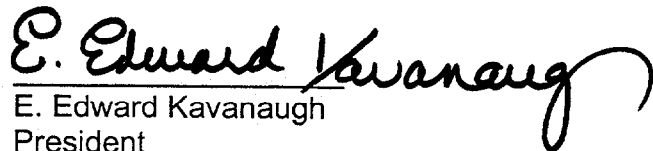
D. Economic Impact

An economic impact will be submitted if requested by the Commissioner following review of this petition.

E. Certification

The undersigned certifies that, to his best knowledge and belief, this petition includes all information and views on which the petition relies, and that there are no representative data or information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,


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President

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